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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,687	12/28/2005	Shigeto Uchiyama	Q92435	3798

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
02/25/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/562,687	UCHIYAMA ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1, 3-9, 11-12 and 14-15* is/are pending in the application.

4a) Of the above claim(s) *9,11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 2/9/11 is acknowledged.

To conform with standard practice and for the sake of clarity, independent claims should be amended to start with --A-- and dependent claims to start with --The-.

Claims 1, 3-8 and 14-15 are being considered on the merits.

Claims 9, 11, 12 are withdrawn from consideration as directed to a non-elected invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4-8 and 14-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 6-14 of copending Application No. 12/095828. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to compositions comprising any bacterial cell, including bacterial strains of L. garvieae, that are capable of producing equol from daidzein and daidzein compound containing ingredients, including foods or pharmaceuticals.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

In the absence of a terminal disclaimer, the rejection is maintained. No claims are allowable at this time.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-8 and 14-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

M.P.E.P. § 2163 recites, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention… one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

M.P.E.P. §2163 recites, "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such

identifying characteristics, sufficient to show the applicant was in possession of the claimed genus…when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. **For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.**"

The claims are broadly drawn to an isolated L. garvieae isolated from human stool that has an ability to utilize at least one daidzein such as daidzein glycosides, daidzein, and dihydrodaidzein to produce equol. The specification shows a single strain that has this ability, i.e., strain L. garvieae 20-92.

In addition, there is no guidance in this record as to a reliable and predictable method to isolate further L. garvieae from human stool that have an ability to utilize at least one daidzein such as daidzein glycosides, daidzein, and dihydrodaidzein to produce equol and which are non-pathogenic. The species L. garvieae is recognized to include pathogens See, also, specification, paragraphs [0058]-[0065].

In the specification, Applicants discuss the production of this compound in general and broad terms with respect to Lactococcus garvieae. However, strain L. garvieae 20-92 is the sole strain that has been isolated from human stool by applicant and there is no clear indication on this record how to identify further strains that have the required properties.

Therefore, there is no clear guidance for obtaining random Lactococcus garvieae from human stool having the required "capacity" of producing equol from daidzein products as claimed. Applicant has shown in the specification that L. garvieae 20-92 has the ability to utilize at least one daidzein such as daidzein glycosides, daidzein, and dihydrodaidzein to produce equol. Applicant has not shown the ability or results relating to other members of the species L. garvieae that have the ability to utilize at least one daidzein such as daidzein glycosides, daidzein, and dihydrodaidzein to produce equol as claimed..

See University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene (or promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence), and at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

The disclosed strain of L. garvieae is not representative of the strains within the species L. garvieae isolated from human stool having the ability to utilize at least one daidzein such as daidzein glycosides, daidzein, and dihydrodaidzein to produce equol because there is no known correlation between the possession of this property in a single strain isolated from human stool and the function of the claimed invention that one of skill in the art would recognize. There is no clear indication that any L. garvieae isolated from human stool selected at random would share the required common properties with the one strain obtained. Thus it is not apparent that the disclosure provided is reasonably predictive of the activity of random L. garvieae isolated from stool regarding the ability to utilize at least one daidzein to produce equol.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the claimed invention.

"Test for sufficiency of written description is whether disclosure of patent application relied on reasonably conveys to those skilled in art that inventor had possession of claimed subject matter as of application's filing date; this test **requires objective inquiry into four corners of specification from perspective of person of ordinary skill in art**, and based on that inquiry, specification must describe invention understandable to that skilled artisan and show that inventor actually invented invention claimed." (Emphasis added)Ariad Pharmaceuticals Inc. v. Eli Lilly & Co., 94 USPQ2d 1161 (Fed. Cir. 2010). Thus, Declarations and new references cannot demonstrate possession of a concept after the fact.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Counsel asserts that because the strain of genus Lactococcus garvieae 20-92 having the equol-producing ability is isolated from human stool, it is logical and natural for a skilled artisan to believe that many other strains of the genus Lactococcus garvieae having the same equol-

producing ability exist in human stool, and that such strains can be easily obtained from the environment.

However, the rejection made is not based on ease or difficulty of isolation, but rather on the premise that the isolation of strains having certain specific properties from an environment such as a human stool is an unpredictable art, and that adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. As noted above, M.P.E.P. §2163 recites, "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus…when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

In the instant case no clear correlation is shown between being isolated from human stool and the possession of the required property of having an ability to utilize at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein to produce equol in one single strain and the genus of Lactococcus garvieae strains as claimed.

Therefore the rejection is deemed proper and it is adhered to.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-8 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villani et al. or Fortina et al. or Paludan Muller et al. taken with Setchell et al. and Elliottt et al. for the reasons as stated in the last Office action and the further reasons below.

Each of Villani et al. or Fortina et al. or Paludan Muller et al. disclose isolated strains of a strain of L. garvieae . See, e.g., page 433, col. 1; Table I; page 67, col. 1, respectively.

The references differ from the invention as claimed in that the strains have not been disclosed as isolated from human stool. However, one of ordinary skill in the art would have recognized that a strain that is present in cow's milk and/or in cheese may be present and isolatable from stool of a human that consumed the milk or cheese. Therefore in this regard the site of isolation is not deemed to be distinguishing.

The properties listed in claim 15 appear to be properties shared by all strains of L. garvieae in the absence of evidence to the contrary.

The references differ from the invention as claimed in that the strains have not been disclosed as having an ability to utilize at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein to produce equol.

However, Setchell et al. disclose a composition comprising a strain of Lactococcus which appears to have "an ability to utilize at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein, and dihydrodaidzein to produce equol" . See, e.g., Example 5, which contains soy milk, daidzein and equol.

The Setchell reference differs from the invention as claimed in that the strain disclosed by Setchell et al. is classified as L. lactis rather than L. garvieae.

In addition, Elliottt et al. adequately demonstrate that the classification boundaries between as L. lactis and L. garvieae are not clearly defined. The close taxonomic status demonstrates that the species are clearly closely related, as evidenced also by their capabilities regarding the biotransformation of daidzein and related compounds into equol in compositions such as milk, and soy milk in particular.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to provide a strain of L. garvieae having an ability to utilize at least one daidzein compound selected from the group consisting of daidzein glycosides, daidzein,

and dihydrodaidzein to produce equol as suggested by the teachings of Villani et al., Fortina et al.. Paludan Muller et al., Setchell et al. and Elliottt et al. for the expected benefit of providing a stain capable of the bioconversion of daidzein into equol, a useful pharmaceutical for human administration.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The crux of applicant's arguments is that no evidence was provided to demonstrate that the L. garvieae strain of Setchell et al. has the required ability. In this regard, it is noted that the evidence of record regarding the touted ability pertains exclusively to the deposited strain that L. garvieae 20-92. See, also, the discussion regarding the written description rejection under 35 U.S.C § 112, first paragraph. That a mixed culture was used is not informative as to the specific capabilities of the strain disclosed by Setchell et al.

Applicant argues that it is very likely that the strain of Setchell does not have the required ability to produce equol because equol is not clearly produced. With all due respect, the claims are directed to any L. garvieae "having an ability to utilize certain daidzein compound to produce equol" and not to process of making equol. In addition, claim 1 is directed broadly to any strain of L. garvieae except. The amounts of L. garvieae in composition claims 4-9 and 14 is not disclosed with any particularity. Therefore, a composition containing a strain having "an ability to utilize certain daidzein compound to produce equol" in the context of trace amounts fails to patentably distinguish over compositions wherein such an ability may be lacking.

Applicant argues that in Setchell there is no clear evidence that equol was actually produced by the mixture of the microorganisms. However, "an ability to utilize certain daidzein compound to produce equol" is likely present in the Lactococcus strain of interest and applicant has not shown otherwise with probative evidence..

It must also be emphasized that there is nothing on this record to disclose to one of ordinary skill in the art whether the ability of the disclosed strain of L. garvieae 20-92 to utilize at least one daidzein such as daidzein glycosides, daidzein, and dihydrodaidzein to produce equol

is or is not present in all strains of L. garvieae isolated from human stool as claimed. If the ability is present, then the strains of Villani et al., Fortina et al., Paludan Muller et al., and Setchell et al. would necessarily also possess this property. However, the record is silent in this regard. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cultured strains from the same species L. garvieae differ and, if so, to what extent, from the L. garvieae strains discussed in the references with regard to the ability of producing equol.

Therefore the rejection is deemed proper.

Claim 3 is allowable over the art of record.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651